

Remarks

Claims 1-7, 9-10, 12, 14-17, 19-22, 24, and 26-29 are pending in the present application. Of these, Claims 16, 26, and 27 are withdrawn as a result of a prior Restriction Requirement. Claims 8, 11, 13, 18, 23, and 25 are canceled. New claims 28-29 are added.

Claims 1-15 and 17-25 are rejected. Claim 15 has been amended to correct a scrivener error, in response to the PTO's objections. Claim 20 has been amended in response to the Office's objections. Claim 23 has been canceled in response to the PTO's statement that Claims 22 and 23 are duplicate claims.

Further modifications have also been made to the claims. Claims 1-2, 4-7, 9-10, 12, 14-15, 17, 20-22, and 24-25 are herein amended without prejudice or waiver. Claims 8, 11, 13, and 18 are canceled, without prejudice or waiver.

Support for the amendments can be found as follows:

In claim 1, support for "an effective amount of an inhibitor of a glutamine transport system component can be found at least on paragraph [0036].

In claim 6, support for "the ASC glutamine transport system" can be found at least on paragraph [0037].

In claim 7, support for "the inhibitor of a glutamine transport system component" can be found at least on paragraph [0036]; support for "an inhibitor of the expression of ATB⁰" can be found at least on paragraph [0037].

In claim 9, support for "the inhibitor of expression of ATB⁰" can be found at least on paragraph [0038].

In claim 10, support for "wherein the polynucleotide is an siRNA" can be found at least on paragraph [0038].

In claim 12, support for "wherein the siRNA consists essentially of a sequence set forth in SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, or SEQ ID NO: 6" can be found at least on claim 12 as originally filed.

In claim 14, support for "wherein the siRNA consist essentially of a sequence as set forth in SE ID NO: 3" can be found at least on claim 14 as originally filed.

Support for claim 15 as amended can be found at least on claim 15 as originally filed and paragraph [0105].

In claim 17, support for “wherein the polynucleotide consists essentially of a sequence as set forth in any one of SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5 and SEQ ID NO:6” can be found at least on claim 17 as originally filed and paragraph [0105].

Claim 22 finds support at least on paragraph [0105].

In claim 24 support for “an inhibitor of a glutamine transport system component” can be found at least on paragraph [0036].

Support for claim 28 can be found at least on paragraph [0105].

Support for claim 29 can be found at least on paragraph [0105].

Priority

In the Office Action, the PTO alleges that Applicant has not complied with 35 U.S.C. §120 and is therefore not entitled to the priority date of Provisional Application No. 60/484,728, in that this application allegedly does not provide description of SEQ ID NO:3.

Applicant requests reconsideration and withdrawal of the rejection of priority for claims 1-7 and 9 because these claims do not specifically teach SEQ ID NO:3. However, claims 1-7 and 9 are supported in the original claims of Application No. 60/484,728, at least on page 53. Claims 1-4 are supported in the Specification of Application No. 60/484,728, at least on pages 10 and 47-48. Claim 5 is supported at least by text on pages 29 and 47-48 and in Figures 1 and 11 in the Specification of Application No. 60/484,728. Claims 6, 7 and 9 are supported at least by page 47-48 and Figure 11 in the Specification of Application No. 60/484,728. These claims thus have priority to the filing date of Application No. 60/484,728 of July 3, 2003, and Applicant requests withdrawal of the PTO’s determination of a priority date of June 30, 2004 and recognition of the priority date of July 3, 2003.

Election/Restrictions

In the Office action, the PTO states, and Applicant acknowledges, that Applicant elected Group 5 and polynucleotide sequence SEQ ID NO: 3 in response to a previously issued Restriction Requirement, which is now made final.

Claim Objections

In the Office action, the PTO states that Claims 8 and 20 are objected to because they refer to a single independent claim in the plural sense. In the present paper, claim 8 is canceled and claim 20 has been corrected as required by the PTO. Thus, Applicant requests withdrawal of this objection.

The PTO states that Claims 22 and 23 are duplicate claims and has required correction. In compliance, the Applicant has canceled Claim 23 and therefore requests withdrawal of this objection.

In the Office Action, the PTO states that, should claims 11 and 13 be found allowable, claims 12 and 14 will be objected to under 37 C.F.R. §1.75 as being substantial duplicates thereof. Applicant requests reconsideration and withdrawal of the objection, because the PTO mis-states the law. In the Office Action, the PTO states that M.P.E.P. §2111.03 considers the phrases “consisting essentially of” and “comprising” to be equivalent. Applicant respectfully reminds the PTO that M.P.E.P specifically states the inequality of these two phrases. The M.P.E.P. states:

The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004).

--M.P.E.P §2111.03

The M.P.E.P. further states that:

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original).

And

"A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998).

--M.P.E.P §2111.03

In this case, the claims use different transitional phrases with different meanings as set forth in the M.P.E.P. Nonetheless, to advance prosecution, Applicant cancels Claims 11 and 13 in this paper, without prejudice or waiver.

Rejection of claims under 35 U.S.C. §102(b)

In the present Office Action, the PTO rejects claims 1-3 and 6 under 35 U.S.C. §102(b) over Kilberg, et al., *J. Biological Chemistry* 255: 4011-4019 ("Kilberg") as evidenced by Han, et al., U.S. Patent 5,891,864 ("Han"). Applicant requests reconsideration and withdrawal of the rejection, because neither Kilberg nor Han teach all elements of the claims.

To anticipate a claim, a reference must disclose each and every element of the claim. MPEP §2131. In this case, independent claim 1, and claims 2, 3 and 6 by dependence, are directed to methods of inducing apoptosis with an effective amount of an inhibitor of a glutamine transport system component. However, neither Kilberg nor Han teaches or suggests inducing apoptosis. Thus, Applicant requests reconsideration and withdrawal of the rejection of claims 1-3 and 6 under 35 U.S.C §102(b) over Kilberg and Han.

In the present Office action, the PTO rejects claims 1-3 and 5-8 under 35 U.S.C. §102(b) over Bode et al., *Surgery*, 124:260-268 ("Bode"). Applicant requests reconsideration and withdrawal of the rejection, because Bode does not teach all claim elements.

To anticipate a claim, a single reference must disclose all elements of the claim. In this case, independent claim 1, and claims 2, 3 and 5-8 by dependence, are directed to methods of inducing apoptosis with an effective amount of an inhibitor of a glutamine transport system component. However, Bode does not teach or suggest inducing apoptosis. Thus, the Applicant requests reconsideration and withdrawal of the rejection of claims 1-3 and 5-7 under 35 U.S.C. §102(b) over Bode.

Rejection of Claims under 35 U.S.C. §103(a)

Claims 1-8 and 24 are rejected under 35 U.S.C. §103(a) as allegedly obvious in view of Bode, *supra*. Applicant requests reconsideration and withdrawal of the rejection of claims 1-8 and 24 under U.S.C. §103(a), because the PTO has not set forth a *prima facie* case for obviousness.

To establish a case of *prima facie* obviousness of a claim, the PTO must show that cited references a) teach or suggest each element of the claim; b) set forth a teaching, suggestion, or motivation to combine the elements; and c) provide a reasonable expectation of success. M.P.E.P. §2143. In addition, the PTO must support a conclusion of *prima facie* obviousness on the basis of teachings in the references cited, and not on impermissible hindsight. M.P.E.P. §2145 X.A.

In this case, the PTO has not established a *prima facie* case of obviousness, at least because the PTO has not shown that Bode teaches inducing apoptosis, whereas all of claims 1-7 and 24 include elements of inducing apoptosis. Furthermore, the PTO states that “this step [inhibition of ATB⁰] is considered to have the effect of inducing apoptosis, absence evidence to the contrary.” Office action, p. 6. The PTO cites no text in Bode teaching or suggesting induction of apoptosis by inhibition of ATB⁰. This conclusion is thus reached by the PTO only by impermissible hindsight. Accordingly, Applicant requests reconsideration and withdrawal of the rejection of Claims 1-7 and 24 under 35 U.S.C. §103(a).

In the Office action, the PTO has rejected claims 1-15 and 17-25 as obvious over Bode, *supra* in view of Khvorova *et al.*, US Patent Application Publication 20070031844 (“Khvorova”) Applicant request reconsideration and withdrawal of the rejection, because the PTO has not established a *prima facie* case of obviousness for these claims.

To establish a case of *prima facie* obviousness of a claim, the PTO must show that cited references a) teach or suggest each element of the claim; b) set forth a teaching, suggestion, or motivation to combine the elements; and c) provide a reasonable expectation of success. M.P.E.P. §2143.

In this case, each of the claims includes, either directly or by dependence, the claim element of the induction of apoptosis. However, the PTO does not cite any text in either Bode or Khvorova that teaches or suggests induction of apoptosis. Rather, the PTO asserts, without support, that "One would reasonably expect success in using the nucleotide for ATB0 gene inhibition because Khvorova, et al. teach that the siRNAs of their invention are useful as therapeutic agents against disease." Office action, page 8. The PTO therefore conflates the concepts of gene inhibition with apoptosis, and furthermore cites no teachings in the references indicating that inhibition of gene expression is necessary or sufficient to induce apoptosis. Therefore, the PTO has not established a *prima facie* case of obviousness, and Applicant accordingly requests reconsideration and withdrawal of the rejection.

CONCLUSION

Applicant respectfully requests withdrawal of the objections and rejections and believe that the claims as presented represent allowable subject matter. All claim amendments, withdrawals and cancellations are made without prejudice or waiver. Applicant welcomes a telephone interview to expedite prosecution.

A one-month extension of time is requested under 37 CFR §1.136(a) with the accompanying small entity fee of \$60 as set forth in 37 CFR §1.17(a). A credit card payment form authorizing payment of this fee is enclosed. Commissioner is hereby authorized to deduct any deficiency not covered by this credit card payment or to credit any overpayment with respect to this application to deposit account number 19-3140.

Respectfully submitted,

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